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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/494,297 01/31/00 PODBIELSKI

A P06628US0/BA

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HM22/0307

EXAMINER

MINNIFIELD, N

ART UNIT

PAPER NUMBER

1645

DATE MAILED:

03/07/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.
09/494,297

Applicant(s)

PODBIELSKI

Examiner

N. M. Minnifi Id

Group Art Unit

1645



☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1035 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-18 _____ is/are pending in the application

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-18 _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

☒ CRF NOTICE

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Sequence Requirements

1. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Full compliance with the sequence rules is required in response to this office action. A complete response to this office action should include both compliance with the sequence rules and a response to the election/restriction requirement set forth below. Failure to fully comply with *both* these requirements in the time period set forth in this office action will be held non-responsive.

Election/Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
- I. Claims 1-4, drawn to nucleic acid molecule, classified in class 536, subclass 23.1.
 - II. Claims 5-7, drawn to a protein, classified in class 530, subclass 300, 350.

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- III. Claim 8, drawn to an antibody, classified in class 530, subclass 387.1.
 - IV. Claims 9 and 10, drawn to a diagnostic kit, classified in class 435, subclass 975.
 - V. Claim 11, drawn to pharmaceutical composition (comprising protein), classified in class 424, subclass 244.1.
 - VI. Claim 12, drawn to pharmaceutical composition (comprising antibodies), classified in class 424, subclass 150.1, 165.1.
 - VII. Claims 13, 14 and 18, drawn to methods of treating/preventing infection administering protein, classified in class 424, subclass 184.1.
 - VIII. Claim 15, drawn to , methods of treating/preventing infection administering antibodies classified in class 424, subclass 130.1.
 - IX. Claims 16 and 17, drawn to methods of reducing infection in a medical device , classified in class 424, subclass 422.
2. The inventions are distinct, each from the other because of the following reasons:

Inventions VII, VIII and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP. § 806.04, MPEP. § 808.01). In the instant case the different inventions are different methods that have different methods steps, modes of operation and effect. For example, the mode of operation for treating or preventing infection by

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administering a protein is different from administering an antibody; which is different from reducing infection on medical devices.

Inventions I, II, III, and IV are drawn to different products. The claims of Invention I are drawn to a nucleic acids, those of Invention II are drawn to proteins, the Invention III are drawn to antibodies, and that of Invention IV to diagnostic kit. The inventions can be shown to be distinct because they are made by different methods and because they are physically and functionally distinct chemical entities.

Inventions II and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP. § 806.05(h)). In the instant case the protein of Invention II can be used in diagnostic methods or affinity purifications or screening assays.

Inventions III and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP. § 806.05(h)). In the

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instant case the antibodies of Invention III can be used in diagnostic methods or immunoaffinity purifications or screening assays.

Inventions V and VII are related as product and process of use. Inventions VI and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP. § 806.05(h)). In the instant case the products can be used in diagnostic methods or affinity purifications or screening assays.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for one Group is not required for another Group, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

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3. This application contains claims directed to the following patentably distinct species of the claimed invention:

- a.) Cpa1 (SEQ ID NO:1, NA; SEQ ID NO:2, AA) and
- b.) Cpa49 (SEQ ID NO:3, NA; SEQ ID NO:4, AA)

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, collagen binding protein is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions

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unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).


Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is (703) 305-3394. The examiner can normally be reached on Monday-Thursday from 7:00 AM-4:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette R. F. Smith, can be reached on (703) 308-3909. The fax phone number for Technology Center 1600 is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

N. M. Minnifield

March 2, 2001


NITA MINNIFIELD
PRIMARY EXAMINER 3/2/01